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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Bernhard D Saxe
Foley & Lardner
Washington Harbour
3000 K Street NW Suite 500
Washington, DC 20007-5109

EXAMINER

RAO, MANJUNATH N

ART UNIT

PAPER NUMBER

1652

DATE MAILED: 07/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/869,155

Applicant(s)

SIBBESEN ET AL.

Examiner

Manjunath N. Rao, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 11, 21, 26-34, 36, 38, 39 and 41 is/are pending in the application.
- 4a) Of the above claim(s) 1-8, 11, 27-34, 36, 39 and 41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21 and 26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 October 2001 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☒ Certified copies of the priority documents have been received in Application No. PCT/IB99/02071.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8. 6) ☐ Other:

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DETAILED ACTION

Claims 1-8, 11, 21, 26-34, 36, 38-39, 41 are presently pending in this application. Claims 21 and 26 are now under consideration. Claims 1-8, 11, 27-34, 36, 39-39 and 41 remain withdrawn from consideration as being drawn to non-elected invention.

Election/Restrictions

Applicant's election with traverse of Group III, claim 21 in Paper No. 11 is acknowledged. The traversal is on the ground(s) that coexamination of all of claims 21, 26-30 and 41 along with claims 1-8 and 11, would not be a undue burden on the Examiner. This is not found persuasive because as explained in the previous Office action, these claims have been grouped as they form distinct inventions. While claim 21 is drawn to an inhibitor of a xylanase which is structurally and functionally different from the xylanase enzyme claimed in claims 1-8 and 11. The searches for these groups will have to be independent searches and they are not co-extensive. Furthermore, the searches will involve extensive non-patent literature as well. However, in view of the applicants request, Examiner has now included claim 26 as a method of use of the xylanase-inhibitor in the elected group III. Therefore, claims 21 and 26 are now under examination.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-8, 11, 27-34, 36, 39-39 and 41 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention, the requirement having been traversed in Paper No. 11.

Priority

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in parent Application No. PCT/IB99/02071, filed on 12-17-1999. However, Examiner has not granted the priority date of 12-23-1998 as applicants have not provided the foreign priority document UK 9828599.2 in support for the above date. Examiner acknowledges the submission of UK 9907805.7 filed on 4-6-199 which provides support for the xylanase inhibitor claimed in the instant application.

Drawings

Drawings submitted in this application are accepted by the Examiner for examination purposes only.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 21 and claim 22 which depends therefrom are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 21 recites the phrase "obtainable from". The metes and bounds of this phrase is not clear to the Examiner. It appears that applicants meant to recite "isolated from". If this is so amending the claim accordingly would overcome this rejection.

Claim 22 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 22 recites the phrase "(if at all)". It is not clear to the Examiner as to what applicants mean by this phrase. Correction is required.

Claim 22 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: determination of the degree of resistance as opposed to the "extent of the inhibition" as recited in part (b).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 21 and 26 are rejected under 35 U.S.C. 102(a) as being anticipated by Debyser (a) et al. (J. Cereal Sci., 1999, Vol. 30:39-43). This rejection is based upon the public availability of a printed publication. Claims 21 and 26 of the instant application is drawn to an endo- β -1,4-xylanase inhibitor isolated from wheat flour, wherein the inhibitor has a molecular weight of about 40 kDa as measured by MS or SDS PAGE, wherein the inhibitor has a pI of about 8 to about 9.5, wherein the inhibitor comprises one or more amino acid sequences presented as SEQ

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ID NO:13 through 19 and a method of using the inhibitor for determining the degree of resistance of the xylanase to the inhibitor.

Debyser(a) et al. disclose a xylanase inhibitor called as TAXI isolated from wheat flour and determine the degree of resistance of the xylanase towards the inhibition as well. The reference does not explicitly disclose that the inhibitor protein has a molecular size of about 40 kDa or a pI of about 8-9.5 or that it comprises the amino acid sequences with SEQ ID NO:13 through 19. However, Examiner takes the position that such characteristics of a protein are inherent characteristics and therefore the xylanase inhibitor disclosed by Debyser et al. and that claimed in the instant application are one and the same. Thus Debyser et al. anticipate claims 21 and 26 as written. Since the Office does not have the facilities for examining and comparing applicants' protein with the protein of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same material structural and functional characteristics of the claimed protein). See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald et al.*, 205 USPQ 594.

Claims 21 and 26 are rejected under 35 U.S.C. 102(a) as being anticipated by Debyser (b)et al. (J. Am. Soc. Brew. Chem., 1997, Vol. 55(4):153-156) or Debyser (c) et al. (WO 98/49278, 11-5-1998) or Rouau et al. (J. Cer. Sci., 1998, Vol. 28 :63-70). This rejection is based upon the public availability of a printed publication. Claims 21 and 26 of the instant application is drawn to an endo- β -1,4-xylanase inhibitor isolated from wheat flour, wherein the inhibitor has a molecular weight of about 40 kDa as measured by MS or SDS PAGE, wherein the inhibitor has a pI of about 8 to about 9.5, wherein the inhibitor comprises one or more amino acid

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sequences presented as SEQ ID NO:13 through 19 and a method of using the inhibitor for determining the degree of resistance of the xylanase to the inhibitor.

Debyser (b) et al. and Rouau et al. disclose a xylanase inhibitor isolated from wheat flour and determine the degree of resistance of the xylanase towards the inhibition as well. The reference does not explicitly disclose that the inhibitor protein has a molecular size of about 40 kDa or a pI of about 8-9.5 or that it comprises the amino acid sequences with SEQ ID NO:13 through 19. However, Examiner takes the position that such characteristics of a protein are inherent characteristics and therefore the xylanase inhibitor disclosed by Debyser et al. and that claimed in the instant application are one and the same. Thus Debyser et al. anticipate claims 21 and 26 as written. Since the Office does not have the facilities for examining and comparing applicants' protein with the protein of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same material structural and functional characteristics of the claimed protein). See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald et al.*, 205 USPQ 594.

Debyser (c) et al. disclose a xylanase inhibitor isolated from wheat flour and also determine the degree of resistance of the xylanases towards the inhibition. The reference discloses that the inhibitor has a molecular weight between 40-43 kDa as determined by SDS PAGE. The reference also discloses N-terminal sequence of the xylanase inhibitor. The reference does not explicitly disclose the pI values of the inhibitor protein. Because the reference discloses a xylanase inhibitor that is identical in its source and molecular size and because characters such as pI value and the amino acid sequence of a protein are inherent

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characteristics, Examiner takes the position that the protein in the reference and the protein claimed in the instant application are one and the same. An argument against the above rejection that the reference does not disclose or comprise the amino acid sequences with SEQ ID NO:13-19 would not be persuasive to overcome the above rejection because, the reference discloses N-terminal sequence and the amino acid sequences claimed as being comprised of are partial internal fragment sequences which constitute the inherent characteristic of the protein in the reference. Furthermore, since the Office does not have the facilities for examining and comparing applicants' protein with the protein of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same material structural and functional characteristics of the claimed protein). See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald et al.*, 205 USPQ 594.

Conclusion

None of the claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manjunath Rao whose telephone number is (703) 306-5681. The Examiner can normally be reached on M-F from 7:30 a.m. to 4:00 p.m. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, P.Achutamurthy, can be reached on (703) 308-3804. The fax number for Official Papers to Technology Center 1600 is (703) 305-3014.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


MANJUNATH N. RAO
PATENT EXAMINER

Manjunath N. Rao. Ph.D.
July 17, 2003